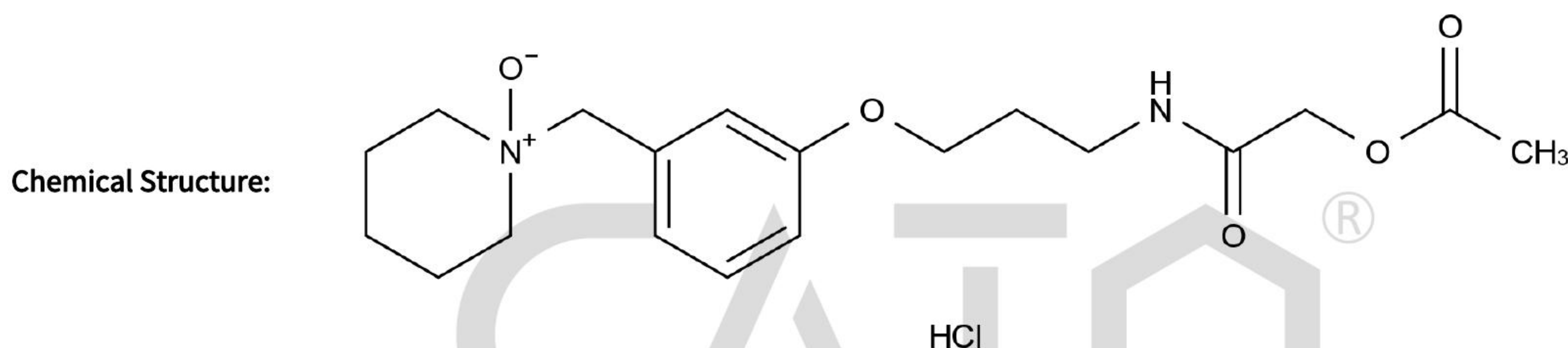


Certificate of Analysis

Reference Material & Standard

Product Name:	Roxatidine Impurity 82 HCl	Catalogue Number:	C4X-121382
Synonyms:	N/A	Lot Number:	1013-RG-0057
CAS Number:	N/A	Expiry Date:	Jan 07, 2029
Molecular Formula:	C ₁₉ H ₂₈ N ₂ O ₅ HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	364.44 36.46		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	97.602%
Water Content	Karl Fischer	0.94%
Residual Solvents	NMR	1.57% methanol
Assay		95.2%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Oct 14, 2025

Date: Oct 14, 2025

Date: Oct 14, 2025



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